

Remarks/Arguments:

Claims 1 and 3-9 and 20-26 are pending in the application. Claim 27 is new, and claims 1, 20, and 26 are currently amended. Support for new claim 27 and the amendments can be found throughout the description in the original specification and as shown, for example, in the Figures. No new matter has been added.

35 U.S.C. §103

Claims 1, 3-9, 22, 24, and 26 stand rejected as obvious over U.S. Pat. No. 6,103,536 (Geisberg) in view of U.S. Pat. No. 4,943,522 (Eisinger), and claims 20, 21, 23, and 25 stand rejected as obvious over Geisberg and Eisinger and further in view of U.S. Pat. No. 6,100,099 (Gordon). Applicants respectfully traverse these rejections, which fail to establish *prima facie* obviousness because the proposed combination of references do not provide all of the features of the claimed invention. In particular, an element required in Geisberg, which would affect the basic and novel characteristics of the claimed invention, is not present in the claimed invention.

"To establish a *prima facie* case of obviousness, ... the prior art reference (or references when combined) must teach or suggest all the claim limitations." M.P.E.P. §2143. The transitional phrase "consisting essentially of" limits the scope of a claim to the elements specified and those that do not materially affect the basic and novel characteristics of the claimed invention. See *In re Herz*, 537 F.2d 549, 551-52 (CCPA 1976). See also M.P.E.P. 2111.03.

Claim 1, as currently amended, recites, in part, a device *consisting essentially of* a single membrane having an application zone for the application of the blood sample, at least one group of at least two indicator zones, each indicator zone comprising a bonding element which is able to bind to the blood group antigen to be tested for, and at least one absorption region.

The claimed invention does not include a "particle zone" or "particulate zone." Geisberg, however, requires the presence of a particle or particulate zone in every embodiment described. In particular, Geisberg describes a device comprising a solid support containing a sample application zone, a particle zone, and one or more signal ratio areas. See e.g., col. 3, lines 33-36; col. 7, lines 57-62; col. 8, lines 20-23; and the Figures of Geisberg. This particulate zone contains large particles (metal colloids, liposomes, latex, etc.) that the claimed devices do not use or require. See col. 5, lines 17-44 of Geisberg. The particle zone of Geisberg contains one or more populations of particles capable of being transported along the solid support through

the one or more signal ratio areas by the sample solution suspected of containing an analyte. Col. 3, lines 38-41 of Geisberg. Geisberg states: "It is imperative that the particles and the sample solution suspected of containing the analyte first go through the first signal zone before entering the second signal zone." Col. 12, lines 63-66 of Geisberg. Therefore, the particle zone is a necessary and essential element in the device disclosed in Geisberg. There is no particle or particulate zone in the claimed invention, and the addition of one would affect the basic and novel characteristics of the device.

Accordingly, a *prima facie* case of obviousness has not been shown at least because an element required in Geisberg, which would affect the basic and novel characteristics of the claimed invention, is not present in claim 1. Therefore, Applicants respectfully submit that claim 1 is allowable. Claims 3-9, 22, and 24 depend, directly or indirectly, from claim 1 and should each be allowable as dependent thereon.

Independent claim 20, while not identical to claim 1, recites similar features including a device consisting essentially of a single membrane having an application zone for the application of the blood sample, at least one group of at least two indicator zones, each indicator zone comprising a bonding element which is able to bind to the blood group antigen to be tested for, and at least one absorption region. The particle zone or particulate zone of Geisberg is similarly not present in claim 20. Thus, claim 20 and claims 21, 23, and 25, which depend therefrom, should be deemed allowable for at least the reasons set forth above.

Independent claim 26, while not identical to claim 1, also recites similar features including a device consisting essentially of a single membrane having an application zone for the application of the blood sample, at least two groups of at least two indicator zones, each indicator zone comprising a bonding element, which is able to bind to the blood group antigen to be tested for, and at least two absorption regions. The particle zone or particulate zone of Geisberg is also not present in claim 26. Thus, claim 26 should be deemed allowable as well.

New claim 27 recites, in part, a device *consisting of* a single membrane having an application zone for the application of the blood sample, at least one group of at least two indicator zones, each indicator zone comprising a bonding element which is able to bind to the blood group antigen to be tested for, and at least one absorption region. The transitional phrase "*consisting of*" excludes any element, step, or ingredient not specified in the claim. See *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948) ("*consisting of*" defined as "closing the claim to the inclusion of materials other than those recited except for impurities ordinarily associated therewith"). See also M.P.E.P. 2111.03. In particular, the particulate zone is excluded from

this claim. Geisberg, however, requires a particular zone as discussed above. Accordingly, an element required in Geisberg is not present in claim 27. Therefore, Applicants respectfully submit that claim 27 is allowable.

Double Patenting

The Office Action provisionally rejected claims 1 and 3-9 on the grounds of nonstatutory double patenting over claims 1-3, 7, 11, 12, 14, and 15 in co-pending application 10/563,681. Applicants note the rejection and request continued abeyance pending an indication of allowable subject matter.

Conclusion

Applicants respectfully request reconsideration and withdrawal of the various rejections in view of the amendments and remarks submitted herewith. An early Notice of Allowance is requested.

Respectfully submitted,

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